

# **Development and validation of the Client centered Occupational Therapy service model**

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**Principal Investigator(s):**

Shu-Chun Lee, Master

En-Chi Chiu, PhD

## **Background and Significance**

Occupational Therapy (OT) is one of the mental health services. The service phase includes acute/chronic hospitalization, daycare centers (adolescents, adults, and the elderly), community mental rehabilitation institutions, psychiatric nursing home, and outpatient assessment/treatments. OT provides holistic and continuous mental rehabilitation services at each stage of mental health care. During the acute hospitalization and based on the Model of Human Occupation (MOHO) model, the occupational therapist provides daily activities to assist acute patients with mental illness to develop occupation adaptation to enable and prepare for discharge.

However, the lack of a client-centered OT service model limits the interpretation of the treatment effect and the process of change. This will seriously affect the integrity and continuity of OT services and will limit the development of OT professions.

## **Specific Aims**

The purpose of the study is to develop and validate Client-centered Occupational Therapy Service at Taipei City Psychiatric Center (OT@tcpc) service model to assist clinicians to provide and integrate comprehensive OT services.

## **Research Design and Methods**

Participants who met the inclusion criteria and signed the informed consent were assessed twice, 2 weeks apart, by an occupational therapist in a quiet environment. After the assessment, participants were randomized into two groups in a blinded one-to-one fashion. This project consists of 2 stages. First, based on the MOHO model we use 6 courses with 2 weeks program to develop the OT@tcpc service model. Second, validate two indicate the occupation identity and competence to validate the OT@tcpc service model. We will recruit 70 inpatients with schizophrenia and divided into intervention group, based on MOHO theory, and control group. The Intervention group provided Occupational therapy based on the MOHO theory, while the control group adopted the original Occupational therapy model.

### **Participants:**

Individuals with schizophrenia were recruited from the Songde District of Taipei City Hospital in Taiwan in June 2020.

### **Inclusion Criteria:**

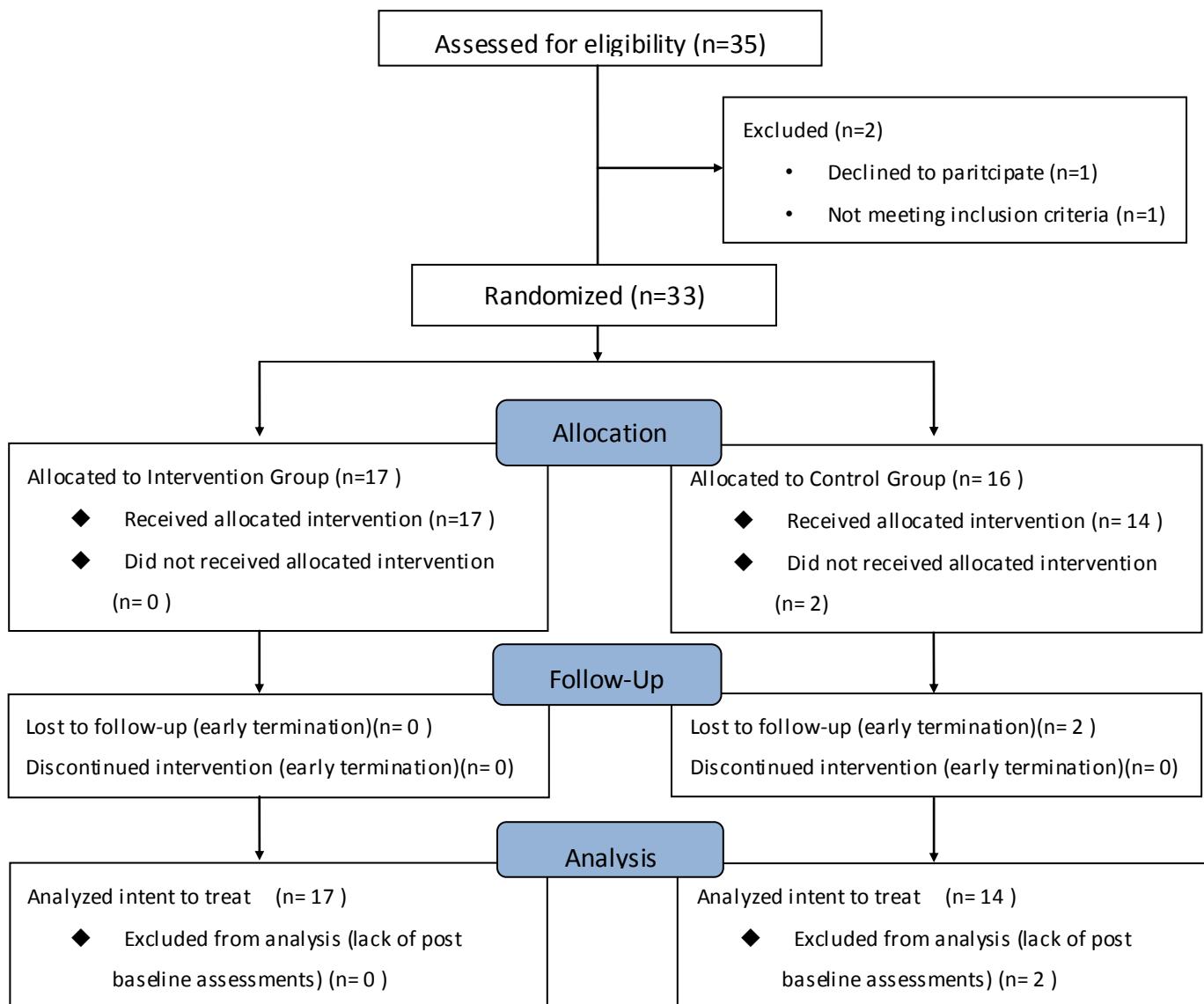
1. Patients diagnosed with schizophrenia according to DSM-5 diagnostic criteria.
2. Aged 20 or older
3. Agree to participate in the study and provide a signed informed consent form

(ICF)

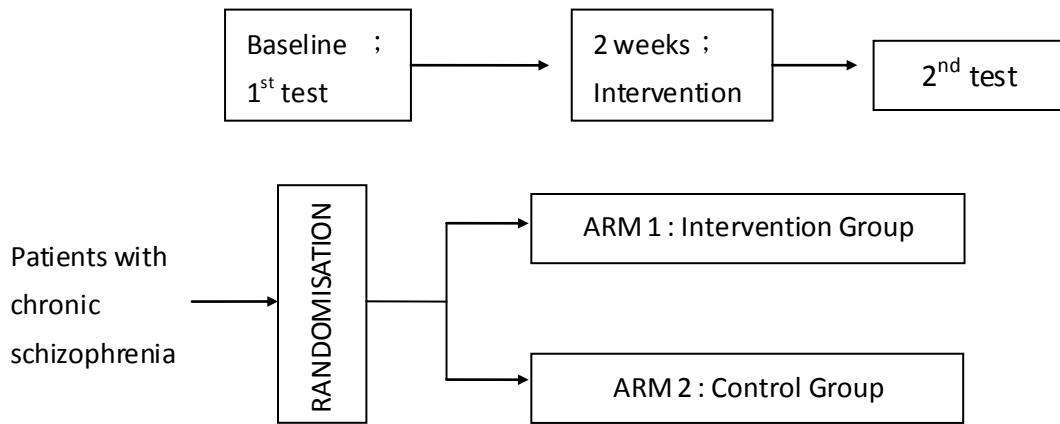
Exclusion Criteria:

1. Diagnosis of intellectual developmental disorders
2. History of severe brain injury
3. Cannot complete the study due to poor cognitive, vision or hand function

The first patient was included in the study June 2020 and the last patient exited the study in July 2020. The recruitment period was one week. The trial was conducted at Songde District of Taipei City Hospital in Taiwan. A total of 35 patients were screened (Fig 1). The planned study period was 1 month. The trial was designed according to Fig 2.



**Fig1. Patient flow.** The outline of the selection and randomization flow of patients in the study.



**Fig 2. Trial design.** Patients with chronic schizophrenia were randomized to the two treatment arms at the Baseline.

#### Statistical methods:

Descriptive summary statistics or frequency counts of demographic and baseline data were presented by treatment arm and overall for the intent to treat (ITT) and per protocol (PP) populations. The PP population was defined as individuals who had completed all scheduled study visits, while the ITT referred to those with data from at least two study visits.

#### Statistical Analysis

A total of 35 patients were screened for participation in the study. One group of 16 people participated in the control group, and the other 17 people participated in the intervention group. In the sample for Intervention group, the mean age was 43.6 years (SD 9.0), and 64.7% of the participants were male. The average duration of illness was 23 years. In the sample for control group, 50% of the participants were also male, the mean age was 43.4 years (SD 9.4), and the average duration of illness was 24.4 years. These two groups were similar in terms of age, onset age, duration of illness, gender, education and marriage. Table 1 presents further details of the participants.

Measure	Intervention group (n=17)	Control group (n=16)	<i>p</i> value
	N (%), Mean $\pm$ SD		
<b>Demographic characteristics</b>			
Age (years)	43.6 $\pm$ 9.0	43.4 $\pm$ 9.4	0.93
Onset age (years)	20.1 $\pm$ 4.8	19.0 $\pm$ 3.8	0.47
Duration of illness (years)	23.0 $\pm$ 8.6	24.4 $\pm$ 8.6	0.65

Gender			0.49
Male	11 (64.7%)	8 (50.0%)	
Female	6 (35.3%)	8 (50.0%)	
Education			0.46
Junior high school	1 (5.9%)	3 (18.8%)	
Senior high school	7 (41.2%)	7 (43.8%)	
College and above	9 (52.9%)	6 (37.4%)	
Marriage			0.51
Single	15 (88.2%)	14 (87.5%)	
Married	2 (11.8%)	1 (6.3%)	
Divorced	0 (0.0%)	1 (6.3%)	
<b>Medical characteristics</b>			
MMSE	27.5 ± 2.5	27.8 ± 2.5	0.80
CGIS	3.6 ± 1.2	3.4 ± 1.6	0.58
LIADL	18.1 ± 4.8	17.8 ± 4.2	0.88
COTES	70.8 ± 7.9	74.9 ± 7.8	0.14
COPM-C	11.3 ± 5.4	9.9 ± 4.6	
COPM-C performance	5.7 ± 2.6	5.1 ± 2.3	
COPM-C satisfaction	5.6 ± 3.0	4.8 ± 2.5	
PSP	52.1 ± 15.9	51.9 ± 12.5	0.97
Socially useful activities	2.5 ± 1.5	2.3 ± 1.1	
Personal and social relationships	3.9 ± 1.3	4.3 ± 1.0	
Self-care	1.4 ± 0.7	1.4 ± 0.7	
Disturbing and aggressive behaviors	1.3 ± 0.5	1.4 ± 0.5	
OPHI-II	66.2 ± 8.0	69.4 ± 6.8	0.24
Occupational Identity	24.9 ± 4.8	25.7 ± 3.4	0.58
Occupational Competence	20.7 ± 2.6	22.1 ± 2.7	0.13
Occupational Behavior			
Settings	20.7 ± 2.7	21.6 ± 2.3	0.28

**Table 1. Demographic and medical characteristics for the two treatment groups.**

The sample statistics presented in this table were mean ± standard deviation (SD) for continuous variables and frequency (percentage, %) for categorical variables. The listed *p*-values of statistical tests were calculated using the Wilcoxon rank-sum test for continuous variables and the Fisher's exact test for categorical variables.

## References:

1. Lee J. Achieving best practice: a review of evidence linked to occupation-focused practice models. *Occup Ther Health Care*. 2010 Jul;24(3):206-22. doi: 10.3109/07380577.2010.483270.
2. Lee SW, Taylor R, Kielhofner G, Fisher G. Theory use in practice: a national survey of therapists who use the Model of Human Occupation. *Am J Occup Ther*. 2008 Jan-Feb;62(1):106-17.
3. Lee SW, Kielhofner G, Morley M, Heasman D, Garnham M, Willis S, Parkinson S, Forsyth K, Melton J, Taylor RR. Impact of using the Model of Human Occupation: a survey of occupational therapy mental health practitioners' perceptions. *Scand J Occup Ther*. 2012 Sep;19(5):450-6. doi: 10.3109/11038128.2011.645553. Epub 2012 Jan 3.
4. Melton J, Forsyth K, Metherall A, Robinson J, Hill J, Quick L. Program Redesign Based on the Model of Human Occupation: Inpatient Services for People Experiencing Acute Mental Illness in the UK. *Occup Ther Health Care*. 2008;22(2-3):37-50. doi: 10.1080/07380570801989382.
5. Landtblom, A. M., Guala, D., Martin, C., Olsson-Hau, S., Haghghi, S., Jansson, L., & Fredrikson, S. (2019). RebiQoL: A randomized trial of telemedicine patient support program for health-related quality of life and adherence in people with MS treated with Rebif. *PLoS one*, 14(7), e0218453.
6. Melton J, Forsyth K, Metherall A, Robinson J, Hill J, Quick L. Program redesign based on the model of human occupation: Inpatient services for people experiencing acute mental illness in the uk. *Occupational therapy in health care*. 2008;22:37-50
7. Liu KP, Ng BF. Usefulness of the model of human occupation in the hong kong chinese context. *Occupational therapy in health care*. 2008;22:25-36
8. Costa A, Othero M. Palliative care, terminal illness, and the model of human occupation. *Physical & Occupational Therapy in Geriatrics*. 2012;30:316-327